OCT 1 0 2000

K002355

510(k) Summary
for
Atom Infa Warmer V-505

1. SPONSOR

Atom Medical Corporation
3-18-15, Hongo
Bunkyo-Ku
Tokyo 113-0033
Japan

Contact Person: Hiroshi Tanaka, Manager, Quality Regulatory Department
Telephone: 03-3815-2311

Date Prepared: August 1, 2000

2. DEVICE NAME

Proprietary Name: Atom Infa Warmer V-505
Common/Usual Name: Infant radiant warmer
Classification Name: Infant radiant warmer

3. PREDICATE DEVICES

The Atom Infa Warmer V-505 is substantially equivalent to the following devices:

- Air-Shields® Delivery Room Warmer (K861781)
- Ohmeda Infant Warmer Systems Models 3000/3300 (K840867/K840858)

4. INTENDED USE

The Atom Infa Warmer V-505 is a radiant warming open-type incubator intended to provide an optimum clinical environment for observation, examination, temperature regulation, and management of neonates. Optional functions include pulse oximetry and oxygen delivery.

5. DEVICE DESCRIPTION

The Atom Infa Warmer V-505 ("V-505") is available in three models.

- V-505HL: containing a treatment table that can be electrically raised and lowered using an elevating pedal at the base of the device
- V-505: containing a treatment table but no electronic elevation function
- V-505ST: containing the warmer element without an attached treatment table

All of the V-505 models are designed to maintain an infant's body temperature by means of infrared radiant heat emitted from a heater located above the mattress. Temperature control is achieved either by manual adjustment of the heater output or by servo control based on changes in the infant's skin temperature. All models of the V-505 may also be purchased with the following optional functions: a pulse oximeter that measures the infant's SpO_2 and pulse rate, an oxygen delivery system consisting of either an oxygen blender or an oxygen flowmeter, and a suction unit. Other device features (depending on the model) include a timer, illumination lamps, an RS232 connector for communication with an external computer, a rotating/tilting canopy, a tilting mattress platform, baby guards, and support column rails for attaching an optional tray set or I.V. pole.

6. SUBSTANTIAL EQUIVALENCE

Atom Medical Corporation makes the claim of substantial equivalence based on intended use, design, operational and technological characteristics, and principles of operation. Atom Medical Corporation believes that the descriptive information, performance test summaries, and certificates of compliance provided in this premarket notification are precise enough to demonstrate the substantial equivalence of the V-505 to the identified predicate devices. The V-505 and the predicate devices are all intended to maintain a newborn's body temperature by radiant heat and to provide a controlled environment for the observation, examination, and management of newborns. The V-505 and the predicate devices all operate in both manual and servo modes for temperature control. All devices also offer a variety of other features including oxygen flowmeter and/or blender, suction control, Apgar timer, tilting mattress, tilting/rotating canopy, illumination lights, and an RS-232 communications module. All devices have similar displays, alarms, and user controls.

7. PERFORMANCE TESTING

Performance testing for the V-505 has been conducted for functional and design verification. This testing demonstrates that the V-505 is in compliance with the following recognized consensus standards.

- IEC 60601-1 (1988-12) Medical Electrical Equipment, Part 1: General Requirements for Safety, Amendment 1 (1991-11), Amendment 2 (1995-03)
- EN 60601-1-2 (1993) Medical Electrical Equipment, Part 1: General Requirements for Safety, Electromagnetic Compatibility-Requirements and Tests
- IEC 60601-2-21 (1994-02) Medical Electrical Equipment, Part 2: Particular Requirements for Safety of Infant Radiant Warmers, Amendment 1 (1996-10)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2000

Atom Medical Corporation
C/O Ms. Sheila Hemeon-Heyer
Senior Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K002355
Trade Name: Atom Infa Warmer V-505
Regulatory Class: II
Product Code: FMT
Dated: August 1, 2000
Received: August 2, 2000

Dear Ms. Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Atom Infa Warmer V-505

Indications For Use:

The Atom Infa Warmer V-505 is a radiant warming, open-type incubator intended to provide an optimum clinical environment for observation, examination, temperature regulation, and management of neonates. Optional functions include pulse oximetry and oxygen delivery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002355

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)